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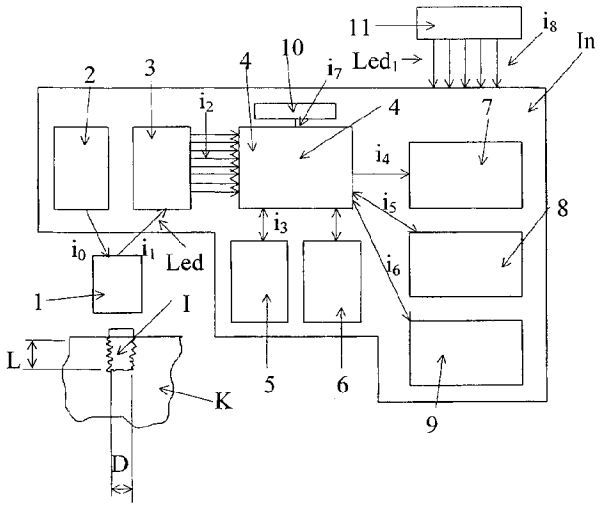
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICE AND METHOD FOR ESTABLISHING STABILITY IN AN IMPLANT OR UNIT



(57) Abstract: For the determination of stability of an implant in bone (K), a vibration effectuating unit (1) is used, which gives a frequency signal A corresponding to the stability. A receiving unit receives this signal and converts it to digital information signal (i2), which relates to the stability. A processing unit (4), receives the digital signal and processes it together with information relating to distortion factors from the current situation, such as implant dimension, surface, material, anatomical site etc. The processing unit gives as output a presentation information (i4), which disregards said factors and therefore representing only the stability. Alternatively, the processed information is stored for comparison with later information, to make it possible to follow the healing process, or otherwise monitor the function of the implant.

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Device and method for establishing stability in an implant or unit.

The invention relates to a device and method for the measurement of implant stability as a function of, amongst other things, the resonance frequency of the implant, of the implant with an attached structure and/or of a transducer in contact with the implant or a structure that is attached to the implant. The invention also relates to establish the stability of an anchorage of a first unit. It also relates to the preamble of claims 1, 2, 3, 9 and 12. Bone anchored threaded any cylindrical metallic, endosseous implants are now widely used in Medicine and Dentistry. Such implants are inserted into a pre-drilled hole in the facial skeleton and used to provide a means of anchorage for a dental or facial prosthesis which may be a single replacement tooth, a bridge, a denture or even a false eye or ear. Implants may be placed as a one or two stage procedure. In a one stage procedure the implant is placed and exposed immediately in, for instance, the patient's mouth. A prosthesis may then be constructed and the implant loaded immediately. This method is less popular because immediate loading carries with it an increased risk of failure as the implant may not be sufficiently stable to distribute the stresses from the prosthesis effectively. In a two stage procedure, the implant is placed in two parts and the implant fixture is buried beneath the soft tissue and left to heal for three to six months before connection of a metal collar or transmucosal abutment. This transmucosal abutment then allows connection of the prostheses. It is generally accepted that the success of a two stage procedure is higher because of the delayed loading.

The key to successful implant placement is achievement of good implant stability. Implant stability is the resistance of an implant to movement and reflects its ability to distribute stresses. The stability of an implant at placement is a function of a number of parameters. These relate to the implant itself, its length, diameter, and surface characteristics. They also relate to the type of surgical procedure, the size of hole that is drilled and the amount of tissue removed. Equally important is the quality of the bone, which may vary from a dense cortical plate in the anterior part of the mandible to an open trabecular network in the posterior part of the maxilla. Following

implant placement stability changes as a healing and remodelling process takes place within the bone. It is likely that there is a degree of stress relaxation following the placement of the implant followed by an inflammatory response with wound healing. Following this there will be remodelling until an equilibrium stage is reached. A successful, osseointegrated implant shows no decrease in the height of bone surrounding it nor a decrease in stiffness. The current most commonly used method for assessing implant performance is the use of radiographs, however these are two dimensional in nature and difficult to reproduce. It has been demonstrated that implant stability and bone height can be related to the first (and higher) resonance frequencies of a transducer attached to the implant. It has also been demonstrated that the resonance frequency could be measured on the implant itself.

A measurement of implant stability is a useful parameter for both the diagnosis of problem implants and the monitoring of implants throughout their lifetime. It is generally referred to in WO92/18053, US 5,518,008, US 5,392,779 and US 4,499,906. Through the prior art it is known to use the resonance frequency as a parameter, but this causes problems when the resonance is used for determing the stability and is affected by another factors than the stability.

The basic parameter for the measurement of implant stability is resonance frequency (F_r). F_r is specific for an implant situation and, as described above, is dependent on a number of different parameters, for instance the geometry and the material of the implant. This means that measurements on different implants can give different resonance frequencies although they have the same stability. In practice, this makes it difficult to evaluate the real stability in the actual case.

It is one objective of the invention to solve this problem and make it possible to determine the true stability in spite of differences between different implants.

When the measurement of implant stability is made indirectly, by measuring the resonance frequency with a transmucosal abutment or other structure mounted on the implant, the geometry of the abutment and/or structure will affect the resulting resonance frequency. This will make it difficult to directly compare measurements of F_r for objects in different situations.

It is a general objective of the invention to solve this problem.

The resonance frequency can have a substantial variation, which means that an instrument that can cover a wide frequency range is necessary. In normal situations, the clinically interesting range is smaller than what is actually possible, leading to difficulties in achieving good resolution in that range. It is an objective of the invention to solve this problem.

For a stability value to be useful to a clinician, the presented value has to be comparable between implants of different types, different lengths and also between situations with different clinical/surgical conditions (for instance the drill hole diameter, the bone quality and the anatomical area).

It is an objective of the invention to solve this problem.

It is of interest to compare stability measurements made at different occasions during the treatment process. It is an objective of the invention to solve this problem.

That mainly can be considered as characteristic for a device according to the invention is, amongst other things, that it contains receiving organs which receives the respective frequency signal and transforms it to a digital information signal which is related to and/or is representing the stability and/or, under the above specific circumstances, distinctive features in the implant situation. Further characteristics are the it works together with organs that contains information which shows or is working with information which represents those distinctive features and that it also contains a calculation unit (for example a microcomputer), or is working together with such a unit which with a software program processes one or more information signal(-s) with the above information. According to the invention, the processing with a preferably mainly known program, results in a presentation information, which could be transferred to a presentation unit which could be separate or included in the calculation unit and arranged to present the stability independent of the implant type, geometry et cetera. It is also referred to the characteristic parts of claims 1, 2 and 3.

The invention proposes i.a. the use of internal memory circuits and/or an external memory unit and/or memory circuits in the transducer. The memory circuits contains in use information about the present implant system, i.e. the distinctive features

of the implant of the patient to be assessed. The memory contents is used in an arithmetic unit (for example a microcomputer), which can be built in the instrument or be external. The arithmetic unit uses the information in the memory circuits to compensate the measurement value for differences in the geometry and other factors between different implant systems.

In one embodiment where, for example, the implant is used with an abutment, information about the dimensions of the specific abutment and/or other specific information are used in the same way to compensate the measurement value for influences from these.

In another embodiment, the system of the invention uses knowledge about which is the clinically interesting frequency range, to map F_r to a scale with good resolution in that range. The scale could run from, for instance 0 to 100.

These previous versions have the form of a system or device, which translates Fr to a compensated value, given the abutment, dimensions (if an abutment is used) and information about the implant system used, as input. It could also be used to compensate for other clinical parameters, such as the diameter of the drilled hole, the quality of the bone, the anatomical area et cetera, which can be added by the clinician or otherwise communicated to the arithmetic unit.

In a further aspect of the present invention there is provides a device as claimed in claim 9 of the claims hereinafter. The device the mentioned receiving organs contains or co-operates with one or more storage units, internal and/or external, which stores the digital information signal, and/or its presentation, for each respective measurement, such that the signal(-s) and/or presentation(-s) is/are reusable in order to be run together or compared with other corresponding information signals and/or presentations that are received at consecutive interactions, separated in time, between the implant(-s) and one or more vibration effectuating unit. It is also referred to the characteristic part of claim 9. According to a yet further aspect of the present invention there is provided a method as claimed in claim 12 of the claims hereinafter.

In one version, stability values are stored in the instrument or in external memory circuits, to make it possible to compare measurements made at different

occasions, and simplify for the clinician and/or let the arithmetic unit make calculations based upon these comparisons.

All suggested solutions are achieved by using hardware to determine the resonance frequency in a specific frequency range, and then using an arithmetic unit together with stored information for determining the stability value.

A working set-up and method according to the invention may look and work according to the attached drawing, which partly and principally shows a longitudinally sectioned view of an implant in bone, and an instrument, in a block diagram, for measuring implant stability.

An embodiment of the present invention will now be more particularly described by way of example with references to the accompanying drawing, which principally discloses components and signals included and attained in the actual apparatus.

The drawing shows a bone K. The implant I has been applied in the bone according to known procedures, and can be selected from a range of diameters D and lengths L. A vibration- or force effectuating and vibration detecting unit (I) is brought in contact with the implant (or an attached structure). The unit is connected or possible to connect to an instrument In, through a connection I.ed. The instrument includes a vibration effectuating unit (2), an A/D-converter (3), an arithmetic unit (microcomputer) (4), one or more memories (5, 6), a presentation unit (7), a memory for storing measurement data (8), and a comparing unit (9).

A frequency signal i_0 is sent from the unit, and a frequency signal i_1, is achieved from the unit (1) when it is activated against the implant (or attached structure). The unit (3) converts the signal i_1 to a digital information signal i_2. The unit (4) which can work with a known program, processes the signal i_2 combining it with the signal i_3 which is representative for distortion factors such as differences in diameter and length (D and L), and more. The result is a presentation signal i_4 which relates only to the stability and not to any of the distortion factors.

The program executes the equation $ISQ=F \times (F_r-F_l) / (F_h-F_l) \times 100$, where ISQ= implants stability.

F= a compensating function which can be linear or non-linear and dependent of the implant geometry, the geometry of the abutment or any other attached structure, clinical conditions et cetera.

F_l= low limit of the clinically relevant frequency range.

F_r= the resonance frequency.

F_h= high limit of the clinically relevant frequency range

F_l preferably has values around 5000 Hz (4500-5500 Hz), and F_h preferably has values around 10000 Hz (9000-11000 Hz).

In a case in which one would use measurements separated in time or measure the stability at two or more occasions, the memory (8) and the comparator (9) is used. Storage of measurements and/or reusable values is indicated with i_5, and the comparing function with i_6. The program in the unit (4) is illustrated as the memory function (6). Also, activating buttons or a keyboard is indicated (10). Control information i_7 can be typed in or received with the keyboard. In the example, the functional components 2-10 are realised in the instrument In. One or more of the components can be external components to which the instrument is attachable at or between the measurement occasions. The instrument can interact with other equipment (for example computer equipment, communication wires, computer network et cetera) which is symbolised with (11) and its connections with Led_1, at which signal i_8 is present.

In an embodiment sensors are used. Each model of sensor is then applied on several calibrating block having a known stability and in which a function is decided by means of a resonance frequency as a function of the stability (defined as ISQ, scaled with 0-100). The factors of this function are programmed in a memory applied in the connecting member of the sensor, together with an individual calibrating factor for each sensor (this one is decided on one or more calibrating blocks after the manufacture of the sensor). If the sensor is to be adapted on distance level, the procedure is the same, apart from the fact that the resonance frequency is measured for several different lengths of dis-

tances on respective calibrating block. Factors, which compensate for the distance length, are also memorised in the memory of the connection member.

In another embodiment only the resonance frequency is shown and after that the sensor is used on a calibrating block with known stability is calibrated. The absolute stability then can be calculated.

In a general embodiment the new apparatus and method can be used for checking the stability of a unit (first unit) which is enclosed in a substrate, foundation, material etc. in a corresponding way as above with implant and bore. The first unit may be mounted and/or is preformed with some elasticity, spring effects, etc. The preambles, characteristic part of the independent claims and the sub-claims can be mutually.

The invention is not limited to the above example, and can undergo modifications within the following claims and the intention of the invention.

CLAIMS

1. A device to enable determination of the stability of the anchorage of a unit, here called first unit, which is anchored in a substrate (material), and wherein the respective first unit can be affected by a vibration effectuating unit, which interacts with the first unit and generates a frequency signal (i1) depending on the stability and distinctive feature(-s) (characteristics), for example dimension, placement, etc., of the first unit, characterised in that the device operates with a digital information signal (i2), which represents said stability and distinctive feature(-s) and is generated in a receiving unit, which receives the frequency signal (i1) and transforms it to said digital information signal (i2), in that information(-s) representing said distinctive feature(-s) is or are, respectively, contained in or can be supplied to one or more information storing means (memories), and in that one or more information signals (i4) are adapted to represent substantially only the stability, which information signal(-s) emanate(-s) from treatment in an arithmetic unit, preferably in a microcomputer, or the digital information signal (i2) and the information(-s) representing the distinctive feature(-s).

2. A device to determine the stability of an implant in the human body, preferably in the facial skeleton, characterised in that the device in use combines a frequency signal or resonance frequency with one or more factors affecting the frequency signal and the resonance frequency, respectively, in a way that the output (i4) of the device substantially depends only on the stability.

3. A device to enable determination of the stability of an implant in the human body, preferably in the facial skeleton, and wherein the respective implant can be affected by a vibration effectuating unit, which interacts with the implant and generates a frequency signal (i1) depending on the stability and distinctive feature(-s) (characteristics), for example dimension, placement, etc., of the implant, characterised in that it operates with a digital information signal (i2), which represents said stability and distinctive feature(-s) and is generated in a receiving unit, which receives the frequency signal (i1) and transforms it to said digital information signal (i2), in that information(-s) representing said distinctive feature(-s) is or are, respectively, contained in or can be supplied to one or more information storing members (memories),

and in that one or more information signals (i4) are adapted to represent substantially only the stability, which information signal(-s) emanate(-s) from treatment in an arithmetic unit, preferably in a microcomputer, of the digital information signal (i2) and the information(-s) representing the distinctive feature(-s).

4. A device according to claim 3, characterised in that it has an integrated member unit, or is possible to attach to an external unit, for example said microcomputer or another computer, by which respective resulting presentation- or storage result may be stored in order for it to be comparable with previous presentation- or storage result(-s).

5. A device according to claim 3 or 4, characterised in, that the calculation of the stability is possible to make with the equation $ISQ=F \times (F_r-F_l) / (F_h-F_l) \times 100$, where ISQ is the implant stability, F is a compensating function which can be linear or non-linear and dependent on the implant geometry, the geometry of any abutment or other structure attached to the implant and/or clinical conditions et cetera, F_l is the lower limit of the clinically relevant frequency range, F_r is the resonance frequency and F_h is the upper limit of the clinically relevant frequency range.

6. A device according to claim 3, 4 or 5, characterised in that F_l has a value of approximately 5000 Hz.

7. A device according to claim 3, 4, 5 or 6, characterised in that F_h has a value of approximately 10000 Hz.

8. A device according to claim 3, 4, 5, 6 or 7, characterised in that F is a non-linear function.

9. A device to enable determination of the stability of an implant in the human body, preferably in the facial skeleton, where an implant vibration effectuating unit is adapted to interact with the implant and generate a frequency signal (i1) dependent on the stability the device having, characterised in, that it operates with a digital information signal, which represents or is related to the stability of the implant, which digital information signal (i2) can be generated in receiving means which transform the frequency signal to said digital information signal, and that it includes or is connected to one or more storage units (memories), which stores respective implants digital infor-

mation signal(-s) or presentation(-s), and in that respective implants stored digital information signal(-s) is/are reusable to be processed together with, or compared to another digital information signal or presentation which is present at consecutive interactions, separated in time, between the implant and the vibration effectuating unit.

10. A device according to claim 9, characterised in, that first and second storage units (memories), stores information- or presentation signal(-s) from two or more occasions, that comparing organs are arranged to compare information signals which has been sent to first and second storage units, and send information depending of the comparison, which represents the actual stability during a period of time of approximately one month and forward, to a presentation means.

11. A device according to claim 9 or 10, characterised in, that it gives an information corresponding to the actual stability for each implant respectively, independent of its length in the bone, dimensions, type, etc.

12. A method to measure the stability of the anchorage of a unit, here called first unit, which is anchored in a substrate (material), where one or more vibration effectuating units is applied to the anchored unit or an attached structure and where one or more stability dependent frequency signals is achieved from the vibration effecting unit(-s), characterised in:

a) that the frequency signal(-s) is/are converted to one or more information signal(-s) representing the stability,

b) that the information signal(-s) is/are processed in a processor means to eliminate distortion factors dependent of the structure of the first unit, implement situation etc. to provide an information output signal that is dependent mainly only on the stability, and

c) that the last mentioned information output signal is transferred to direct use in said measure and/or is stored in one or more memory means to be reused for comparison between two or more set of presentation information, separated in time.

13. A method according to claim 12, characterised in that it detects the stability of an implant in the human body, preferably in the facial skeleton.

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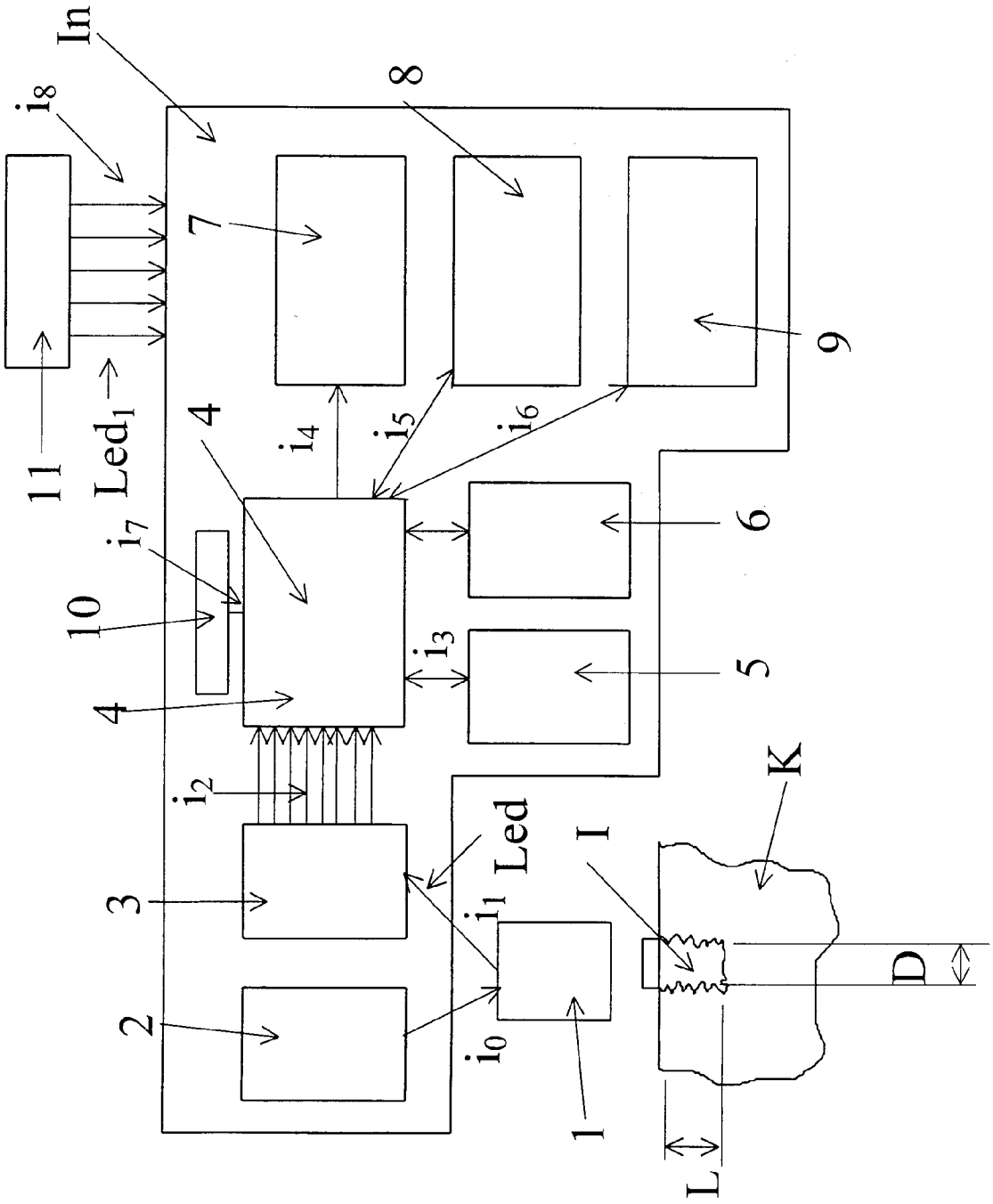

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01762

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/13, A61C 19/04, G01H 13/00, A61F 2/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61C, A61F, G01H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5392779 A (N. MEREDITH ET AL.), 28 February 1995 (28.02.95), column 1, line 38 - column 3, line 10, figure 1	1-13
X	US 4926143 A (K. HARADA ET AL.), 15 May 1990 (15.05.90), column 3, line 34 - line 42, figure 8, abstract	1,12
A		2-11,13
A	US 5518008 A (P.J. CUCCHIARO ET AL.), 21 May 1996 (21.05.96), figure 1, abstract	1-13

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 December 2000	22 -12- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/AE Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01762

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4499906 A (J. WOHLGEMUTH ET AL.), 19 February 1985 (19.02.85), figure 1, abstract -- --------	1-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE00/01762

Box I **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13
because they relate to subject matter not required to be searched by this Authority, namely:

The claim relate to a method of diagnosing the stability of a medical implant. Nevertheless, a search for this claim is made. The examination has been based on the alleged effects of the composition.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

04/12/00

International application No.
PCT/SE 00/01762

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INTERNATIONAL SEARCH REPORT
Information on patent family members

04/12/00

International application No.
PCT/SE 00/01762

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